IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Prakash P. Mathew et al.	§	Confirmation No.:	8841
Serial No.: 10/723,033	§	Group Art Unit:	2624
Filed: November 26, 2003	§	Examiner:	Le, Brian Q.
For: IMAGE-BASED PATIENT DATA OBFUSCATION SYSTEM AND METHOD	§	Atty. Docket:	133276-1 IT/YOD GEMS:0234

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF TRANSMISSION OR MAILING
37 C.F.R. 1.8

I hereby certify that this correspondence is being transmitted by facsimile to the United States Patent and Trademark Office in accordance with 37 C.F.R. § 1.6(d), or is being transmitted via the Office electronic filing system in accordance with 37 C.F.R. § 1.6(a)(4), or is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date below:

3/31/09 — Date

Patrick S. Yoder

Sir:

DECLARATION OF YASEEN SAMARA UNDER 37 C.F.R. § 1.131

I, Yaseen Samara, hereby declare as follows:

1. I am a co-inventor of record for the invention disclosed and claimed in the above-identified patent application.

2. I am currently employed by GE Healthcare, a division of General Electric Company ("GE"), in the Imaging Solutions Group as a Systems Engineer.

3. My business address is 2041A Lincoln Street, Berkeley, California 94709.

4. I, along with the other co-inventors of record, conceived of the subject matter disclosed and claimed in the above-referenced application prior to September 23, 2003. This

conception is evidenced by an invention disclosure document that was prepared by one or more of either myself or the co-inventors of record and submitted to GE in the ordinary course of business prior to September 23, 2003. A true and correct redacted copy of pages 1-7 of this disclosure document is attached hereto as Exhibit A.

5. Prior to September 23, 2003, I received e-mail communications from outside counsel and Mr. Prakash Mathew, a co-inventor of record, discussing the scheduling of a telephonic interview to discuss the disclosure document (Exhibit A). This telephonic interview was carried out between outside counsel and at least one co-inventor, including Mr. Mathew, and is acknowledged by a true and correct redacted copy of the e-mail correspondence attached hereto as Exhibit B.

6. Following the above-referenced telephonic interview, I received a copy of an e-mail communication on August 14, 2003 addressed to outside counsel from Mr. Mathew inquiring about the status of the preparation of the above-identified application. A true and correct redacted copy of this correspondence is attached hereto as Exhibit C.

7. The above-referenced disclosure document (Exhibit A) and the above referenced interview (Exhibit B) clearly indicate that I and the co-inventors of record conceived of the invention ultimately disclosed and claimed in the above-identified application and were in fact in possession of the invention at least as early as August 14, 2003.

8. On August 19, 2003, I received an e-mail communication from outside counsel, in which I was informed that a draft of the above-identified application had not been completed yet, but that outside counsel would complete the draft as soon as possible. This communication can be found in Exhibit C.

9. On November 15, 2003, I received an e-mail communication from outside counsel having attached therewith an initial draft of the above-identified application and

corresponding Assignment and Declaration papers. The e-mail communication requested that I review an initial completed draft of the above-identified application for completeness and accuracy and execute Assignment and Declarations papers. A true and correct redacted copy of relevant portions of this correspondence is attached hereto as Exhibit D.

10. Prior to November 26, 2003, the filing date of the above-identified application, I reviewed the above-identified application and executed the Assignment and Declaration papers. The executed Assignment and Declaration papers were returned to outside counsel on or before November 26, 2003. Constructive reduction to practice of the invention disclosed and claimed in the above-identified application occurred on November 26, 2003.

11. Diligent efforts were made from prior to September 23, 2003 through the filing of the present patent application on November 26, 2003.

12. The subject matter disclosed and claimed in the above-referenced application was conceived while in the United States.

I declare further that all statements made herein are of my own knowledge, are true and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Dated: 3-30-2009 By: Yaseen Samara

Yaseen Samara

EXHIBIT A

GEMS:0234

GE Medical Systems
Invention Disclosure Form

[redacted]

Docket No.: 133276

Mail to: PATENT OPERATION, W-710

Date Received: [redacted]

- **Use as many pages in this word document as necessary.**
- **You may attach additional materials to support this disclosure, for example, Tech Notes and Drawings. Such submitted materials must be referenced in this disclosure form. Each page of these materials must be dated, signed and witnessed in the same manner as this invention disclosure.**

MODALITY: *(e.g. CT, MR, Ultrasound, X-Ray)*

IIS

INVENTION TITLE: *Provide a unique, descriptive title. If you write this disclosure in a language other than English, please provide a title in English as well. Si vous rédigez en français, merci de proposer un titre en anglais et un titre en français.*

Method and system for de-identifying burned in patient data from radiological images

PROBLEM/BACKGROUND: *Describe the problem that is solved by the invention. Assume that the reader has a basic knowledge of your diagnostic imaging modality and related technologies.*

Privacy laws within the medical practice are starting to be heavily enforced (if not already) and a number of regulatory laws mandate the restricted and appropriate disclosure of patient information in all medical records. Radiologists routinely need to, and have been transferring images to referring physicians and colleagues for consultation or teaching, as part of their workflow. Radiological images often contain patient identifying data (mainly text), which would allow a casual or informed observer to associate the image with an individual. Rather than change their established workflow, radiologists look to information system vendors such as GE to provide the tools to de-identify images of patient data to render them compliant to the regulatory law.

Sometimes, the textual annotations are separate layers or tags within an imaging protocol such as DICOM. In such cases, suppressing the display of these tags alone, based on some coded set of rules would be a solution. This however is easy to do and intuitive. A bigger problem arises when the textual information identifying the patient is part of the image pixel set itself, i.e. it has been burned in. In such a case the de-identification problem for radiological images is not trivial and the solution of this would be a considerable benefit to the radiological community.

INVENTORS *(Print or Type Name Below)*	*(Full Signature Below)*	GE	NOT GE	DATE
* Prakash Mathew		X		[redacted]
Yaseen Samara\		X		[redacted]
Vijaykalyan Yeluri		X		[redacted]
Denny Lau		X		[redacted]

* = Primary Contact Inventor (to coordinate with Patent Evaluation Board and Preparing Attorney)

Read and Understood By:

2 WITNESSES (Mandatory) *(Print or Type Name Below)*	*(Full Signature Below)*	DATE

INVENTION DESCRIPTION: *Describe how the invention works and how it solves the problem posed above.*

As described earlier, the problem is that of automatically and conveniently de-identifying "burned in" patient information from radiological images.

Lets clarify what this invention will address…

The most common radiological image interchange method is using the DICOM protocol format. The image is stored and transported in the form of an electronic file. There could be patient identifying information in:

A) The DICOM headers: This is a text portion of the file that encapsulates some metadata regarding the image. Not all information will be visible in the displayed image, but it still represents data that could potentially reveal the identity of the patient. The de-identification method is programmatically coding which information tags will be deleted or retained in an image. [redacted]

B) The DICOM overlay tags: These are also structured information that could be bitmaps that are laid over the actual image. They capture annotations, markers to regions of interests etc. [redacted]

C) The image pixel data. This is the actual pixel data with diagnostic information content. For convenience and record-keeping, patient identifying information is often burned into the exposure. This kind of patient data is hard to programmatically remove because there is no structured way of removing this data. The invention addresses this burned in data de-identification. [redacted]

The solution we propose will be the novel use of **Optical Character Recognition** (OCR) technology for the de-identification of radiological images. OCR technology itself is not new or novel and is quite a mature area. This is routinely and heavily used in the area of text scanning applications. The following is an excerpt from a casual search on the www.About.com website for the term Optical Character Recognition.

OCR (Optical Character Recognition) is the process of turning a picture of words (such as a scan of a typed letter) into an editable document that you can open and use in your desktop publishing software, word processor, or other text editor. Today's OCR packages contain sophisticated support for multiple languages, PDF and HTML output, and format retention.

1) [redacted] has Page Formatter to better retain formatting of pages and recognization of spreadsheets, tables, and other elements. Convert to and from PDF format. The International Voice Read Back reads your text aloud and now recognizes over 100 languages.

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Yaseen Samara		X		[redacted]
Vijaykalyan Yeluri		X		[redacted]
Denny Lau		X		[redacted]

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2) [redacted]
It retains page layout, allows output as Web pages, retains color in photos or graphics, and is Windows 2000 certified. This is a low-cost OCR option.

3) [redacted]
A powerful, but surprisingly inexpensive alternative to some of the better known (and expensive) OCR packages. It reads 52 languages, preserves the page formatting, can scan color and dark backgrounds, has batch processing, and has expert tools for analyzing complicated layouts.

4) [redacted]
From [redacted], the Pro version is recommended for home use but is more advanced than the Home edition. Supports over 100 languages, has built-in spell-checker, handles PDF and HTML and retains document formatting. An under $100US OCR option.

5) [redacted]
The Business Edition includes new and improved PDF Output, supports 56 languages, retains formatting, and outputs to HTML format. Includes scheduled batch processing for busy offices.

The workflow involved might proceed something like this.

1) A radiologist opens a study on a PACS system. He scans through the exams and selects one or more images for sending to another institution, lets say for example, teaching purposes. HIPAA mandates that patient demographic information should not be disclosed.

2) The radiologist now selects the "De-identify including burned text" option in the PACS system.

3) The PACS system now readies the images for sending out. It first negotiates the format of data it needs to send the images in. If DICOM, it creates a copy of the image file, removes the patient demographic information and any overlays in the header. If any other image format like GIF or JPEG, it deals only with the pixel data in the file.

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Yaseen Samara		X		[redacted]
Vijaykalyan Yeluri		X		[redacted]
Denny Lau		X		[redacted]

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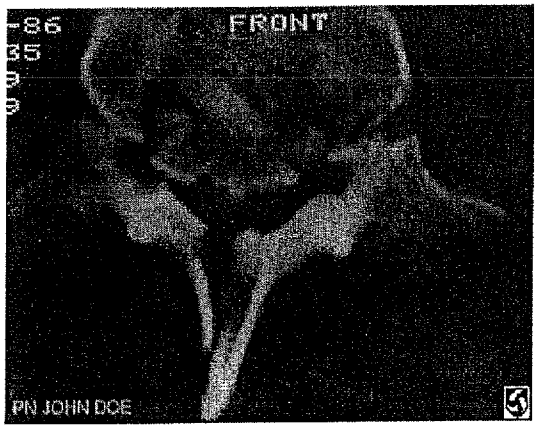
4) In either case, the pixel data is fed into the OCR software program. This can be done progressively, in sections of the image, comprising a strip about 1cm x 5cm or some such small subset. Each section is quickly scanned and the OCR software determines if text is included in these regions. If text is found then an approximate position of the text character is returned. Instead of subsets of strips of the image, the entire image can be fed into the OCR software as well.

5) The PACS system then creates an opaque mask and burns it into the pixels at the locations where text has been recognized. This intensity value of the opaque mask value can be pre programmed into the system. As long as the mask is a single intensity value, the character information underneath is blocked out.

6) The modified image, with the masks burnt in and obscuring the text is then chosen as the image to be sent to the external system. The mask can be patterned or with a distinguishable border so as to clearly communicate to the viewer that information is missing from that region.

DRAWING: *Make as accurate a sketch or computer generated figure of your invention as you can and embed it into or attach it to this form. It need not be a drawing to scale, but should be complete enough to show what you have in mind. If you already have suitable photographs, sketches, software flowcharts or finished drawings, they may be used.*

An example of a radiological image with patient identifying information is shown below: The patient name is visible as text, along with other textual annotations.



After the steps outlined in the invention occur, the resulting image could be modified to look like one of the following:

INVENTORS *(Print or Type Name Below)*	*(Full Signature Below)*	GE	NOT GE	DATE
* Prakash Mathew		X		[redacted]
Yaseen Samara		X		[redacted]
Vijaykalyan Yeluri		X		[redacted]
Denny Lau		X		[redacted]

* = Primary Contact Inventor (to coordinate with Patent Evaluation Board and Preparing Attorney)

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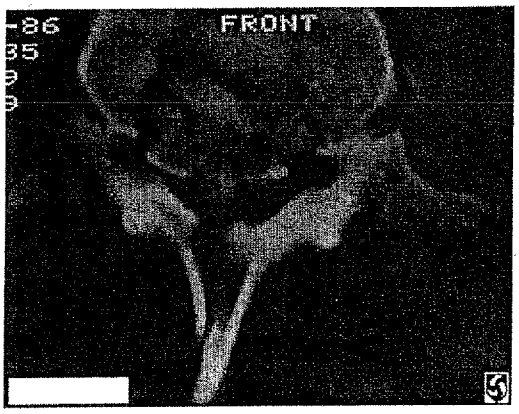
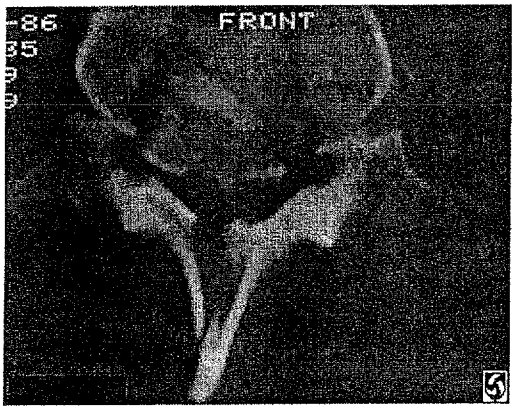
or like

In both cases, the textual information is overlaid out by a burned in mask, thereby anonymizing the identity of the patient involved.

In a related embodiment of the invention, specific rules can be incorporated in the software to recognize and exclude certain useful text which do not identify a patient. Useful text is in the form of measurements or view descriptions such as the phrase "FRONT" on the original image. Using this form of intelligent de-identification we could produce images like the following



or like


In this case, helpful information is retained while the patient identifying information is selectively masked out.

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Yaseen Samara		X		[redacted]
Vijaykalyan Yeluri		X		[redacted]
Denny Lau		X		[redacted]

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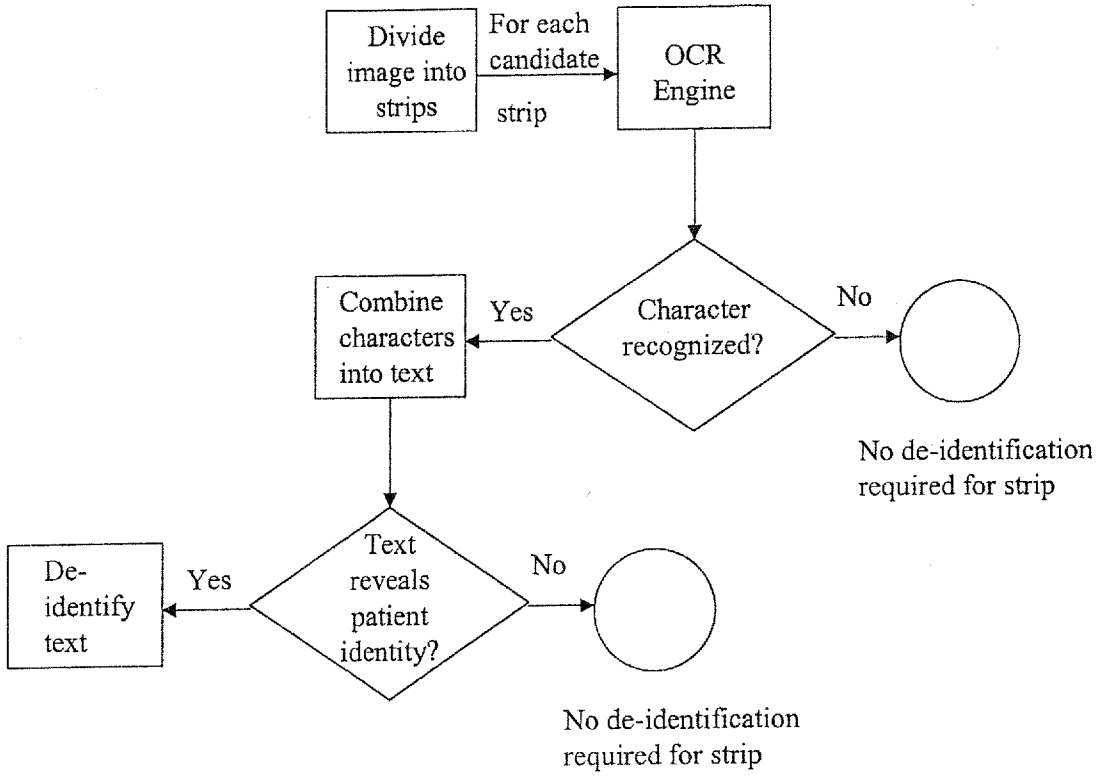
Read and Understood By:

2 WITNESSES (Mandatory) *(Print or Type Name Below)*	*(Full Signature Below)*	DATE

Block Diagram indicating for automatic de-identification



INVENTORS *(Print or Type Name Below)*	*(Full Signature Below)*	GE	NOT GE	DATE
* Prakash Mathew		X		[redacted]
Yaseen Samara		X		[redacted]
Vijaykalyan Yeluri		X		[redacted]
Denny Lau		X		[redacted]

* = Primary Contact Inventor (to coordinate with Patent Evaluation Board and Preparing Attorney)

Read and Understood By:

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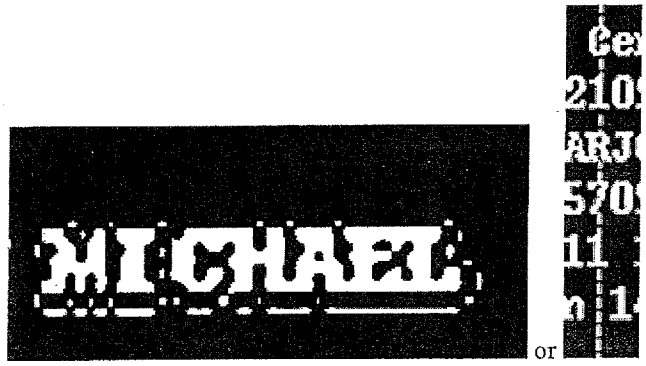
There may be some cases, which will no doubt challenge the capacity of the invention. It will be cases where

1. The text is formatted vertically instead of the usual left to right approach.

   To address this problem ,we would configure the OCR software to read in vertical directions as well. This can be configured in addition to the left to right recognition. The user can choose to configure this or not, but the invention allows for this case.

2. Lines running through the text could obscure the text or it could have extremely poor quality.

   For example,



or

[redacted]

ADVANTAGES OF THE INVENTION: *Describe the benefits of the invention, both in technical terms (e.g., stronger, new application, faster imaging, etc.) and business terms (e.g., cost savings, product efficiency, etc.).*

1. Automatic: This de-identification is done without any manual intervention.
2. Flexibility: The de-identification can be carried out at or in any subset of the image space, based on a set of pre-determined rules.
3. Depending on the OCR software package used, a number of language texts can be recognized and removed.
4. Security: Regulatory and safety guidelines and rules requiring image de-identification of patient information will be satisfied.

INVENTORS *(Print or Type Name Below)*	*(Full Signature Below)*	GE	NOT GE	DATE
* Prakash Mathew		X		[redacted]
Yaseen Samara		X		[redacted]
Vijaykalyan Yeluri		X		[redacted]
Denny Lau		X		[redacted]

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Read and Understood By:

2 WITNESSES (Mandatory) *(Print or Type Name Below)*	*(Full Signature Below)*	DATE

EXHIBIT B

[redacted]

From: Mathew, Prakash (MED) [IMCEAEX-_O=GE_OU=GEMSAM_CN=RECIPIENTS_CN=[redacted]

Sent: [redacted]

To: Pat Yoder

Cc: Samara, Yaseen (GE Healthcare)

Subject: RE: tcon to discuss 133276 and 133277

Hi Pat,
Regarding docket application, 133276, here is an example of [redacted]

It was a pleasure talking to you yesterday...
Thanks
_prakash

-----Original Message-----
From: Pat Yoder [mailto:[redacted]]
Sent: [redacted]
To: Mathew, Prakash (MED); Samara, Yaseen (MED, GEMS-IT)
Subject: RE: tcon to discuss 133276 and 133277

Sounds great Prakash. I'll look over the disclosures and we can try to fit everything in the hour. If we need more time we can schedule more when we talk.

Talk to you then!

Pat

-----Original Message-----
From: Mathew, Prakash (MED) [mailto:[redacted]]
Sent: [redacted]
To: 'Pat Yoder'; Samara, Yaseen (MED, GEMS-IT)
Subject: RE: tcon to discuss 133276 and 133277

How about 10:30-11:30 CST ?
TCON [redacted] #6726510
_prakash

-----Original Message-----
From: Pat Yoder [mailto:[redacted]]
Sent: [redacted]
To: Samara, Yaseen (MED, GEMS-IT); Mathew, Prakash (MED)
Subject: RE: tcon to discuss 133276 and 133277

Guys,

We have a regular meeting from 11:30 to about 1:00 on Thursdays. Can we work around that? (Prakash, you picked my one window on this one.)

Thanks.

-----Original Message-----
From: Samara, Yaseen (MED, GEMS-IT) [mailto:[redacted]]
Sent: [redacted]
To: Mathew, Prakash (MED); 'Pat Yoder'
Subject: RE: tcon to discuss 133276 and 133277

Sounds great! Thursday morning then.

-----Original Message-----
From: Mathew, Prakash (MED)
Sent: [redacted]
To: 'Pat Yoder'; Samara, Yaseen (MED, GEMS-IT)
Subject: RE: tcon to discuss 133276 and 133277

Pat, Yaseen,
I apologize for not responding earlier...
How does Thu [redacted] morning sound?
How about
11:00 - 12:00 CST TCON [redacted] #6726510 (I'm flexible on the time that morning)

_prakash

-----Original Message-----
From: Pat Yoder [mailto:[redacted]]
Sent: [redacted]
To: Mathew, Prakash (MED); Samara, Yaseen (MED, GEMS-IT)
Subject: tcon to discuss 133276 and 133277

Guys,

Any thoughts on this? I'm in all week, but probably need a couple hours advance notice before a tcon.

Thanks!

Pat

Guys,

As Yaseen and I discussed last week, we will be preparing patent applications on the referenced disclosures. I just returned from an extended trip and did review the disclosures during that time. I think the best way to proceed is through a telephone conference during which we can walk through the disclosures and I can flesh out points as needed to move along to the drafting stage.

I will be in all week working on various projects. Could you please just let me know what works for you guys and I'll plan around that. I think we may need as much as a couple of hours to get through the material. One or both of you may with to participate, and I understand that Mathew will probably be the "point person" for these applications.

Thanks, and I look forward to hearing from you.

Pat

Patrick S. Yoder

Fletcher, Yoder & Van Someren
Attorneys at Law
7915 FM 1960 West, Suite 330

Houston, Texas 77070

tel: [redacted]
fax:

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EXHIBIT C

- String E-mail Redacted -

[redacted]

From: [redacted]

Sent: [redacted]

To: [redacted]

Cc: [redacted]

Subject: [redacted]

[redacted]

-----Original Message-----
From: Pat Yoder [redacted]
Sent: Tuesday, August 19, 2003 7:46 AM
To: Mathew, Prakash (MED)
Cc: Samara, Yaseen (MED, GEMS-IT)
Subject: RE: Status of 133276 and 133277 ?

Prakash,

I have these laid out, but just have not completed them yet. Realistically, this will bleed over to next month. I'm personally working on these and will complete them as soon as I can. Please do not hesitate to follow up, but this work is on my very short list for completion.

Thanks,

Pat

-----Original Message-----
From: Mathew, Prakash (MED) [redacted]
Sent: Thursday, August 14, 2003 6:10 PM
To: 'Pat Yoder'
Cc: Samara, Yaseen (MED, GEMS-IT)
Subject: Status of 133276 and 133277 ?
Importance: High

Hi Pat,
Just wondering about the status of the drafts for these cases...
Thanks,
_prakash

-----Original Message-----
From: [redacted]
Sent: [redacted]
To: Mathew, Prakash (MED); Samara, Yaseen (MED, GEMS-IT)
Subject: [redacted]

[redacted]

[redacted]

-----Original Message-----

EXHIBIT D

- String E-mail Redacted -

Pat Yoder

From: Mathew, Prakash (MED) [redacted]
Sent: Tuesday, December 02, 2003 12:26 PM
To: Pat Yoder
Cc: Samara, Yaseen (MED, GEMS-IT)
Subject: RE: (GE docket 133276ITand 133277IT; our file GEMS:0234 and GEMS: 023 5)

Hi Pat,
[redacted]
Thanks,
_prakash

-----Original Message-----
From: Pat Yoder [redacted]
Sent: Wednesday, November 19, 2003 1:31 PM
To: Samara, Yaseen (MED, GEMS-IT); Pat Yoder; Mathew, Prakash (MED)
Subject: RE: (GE docket 133276ITand 133277IT; our file GEMS:0234 and GEMS: 023 5)

[redacted]

Thanks again,

Pat

-----Original Message-----
From: Samara, Yaseen (MED, GEMS-IT) [redacted]
Sent: Wednesday, November 19, 2003 12:16 PM
To: 'Pat Yoder'; Mathew, Prakash (MED)
Subject: (GE docket 133276ITand 133277IT; our file GEMS:0234 and GEMS:023 5)

Pat, Prakash

[redacted]

Yaseen

-----Original Message-----
From: Pat Yoder [redacted]
Sent: Saturday, November 15, 2003 5:50 PM
To: 'Mathew, Prakash (MED)'
Cc: Samara, Yaseen (MED, GEMS-IT)
Subject: draft patent application (GE docket 133276IT; our file GEMS:0234)
Importance: High

Prakash,

As we discussed, we have proceeded to prepare a patent application for the referenced matter,

relating to obfuscation of patient and other data from reconstructed images. Please find attached a copy of the application for your review and for review by the other co-inventors. Also attached are the Assignment and Declaration documents for review and signature by all inventors. I have also attached a .pdf file containing the drawings referred to in the application. Finally, I have attached a Notice regarding our obligations to the Patent and Trademark Office whenever we file new patent applications.

Please review the application for completeness and accuracy, and ask the other co-inventors to do the same. Please keep in mind the points brought out in the attached Notice. Once you have reviewed the application, please call me with any questions or comments at [redacted] If you find the application complete and accurate, please print, sign and date the Assignment and Declaration documents, and have the other co-inventors do the same (noting that the Assignment should be notarized when each of you signs it).

Once signed PLEASE FAX THE ASSIGNMENT AND DECLARATION DOCUMENTS TO ME AT [redacted] (and retain a copy for your records-and in case we need them resent). I would also ask that you drop the documents in the mail to my office at the address below. We can file faxed copies, but must retain originals. IF NECESSARY, THE VARIOUS INVENTORS MAY SIGN DIFFERENT PHYSICAL COPIES OF THE DOCUMENTS. I will need all such copies faxed and mailed back to me, however.

[redacted] Accordingly, I would like to receive the signed documents for filing by MONDAY, NOVEMBER 24, 2003, AT THE LATEST.

Again, should you have any questions or concerns, please do not hesitate to call or email me. [redacted]

Thanks again for your help and hard work. I look forward to your feedback.

Pat

Patrick S. Yoder

FLETCHER YODER
Attorneys at Law
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Houston, Texas 77070

tel: [redacted]
fax: [redacted]

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